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09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/559,401

Applicant(s)

YUYAMA ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. In the amendment filed 7/30/03 in paper number 6, the following has occurred: claims 1-9 have been canceled and claims 10-18 have been added. Now, claims 10-18 are presented for examination.
2. The rejections of claims 1-9 under 35 U.S.C. 112, 35 U.S.C. 102(e), and 35 U.S.C. 103(a) are now moot and, accordingly, withdrawn by the Examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 10, 12, 14, 15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Engleson et al., U.S. Patent No. 5,781,442.

5. As per claim 10, Engleson teaches an apparatus for supporting injection mixing work, said apparatus comprising: a memory operable to store data for supporting injection mixing work, said memory being operable to store a patient predictability data file for storing patient predictability data including at least patient predictable information (see column 5, line 66 – column 6, line 2), an injection prescription data file for storing injection prescription data corresponding to the patient predictability data (see column 6, lines 2-6), and a combination related data file for storing combination related data corresponding to each injection of the

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injection prescription data (see column 6, lines 54-58); a display operable display the data stored in said memory (see column 2, lines 28-31); and a controller operable to determine a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on said display (see column 8, line 66 – column 9, line 12 and Figure 9).

6. As per claim 12, Engleson teaches the apparatus of claim 10 as described above, wherein the combination related data file of said memory includes differentiation data for differentiating transfusion and solely administrated medicament, and wherein said controller is operable to classify the injection contained in the injection prescription data for a patient into transfusion or solely administrated medicament in accordance with the differentiation data and displays it on the display (see column 9, lines 40-52).

7. As per claim 14, Engleson teaches the apparatus of claim 10 as described above, wherein the combination related data file of said memory stores attention information data related to each injection, and wherein the controller is operable to display an attention information in the attention information data on the display corresponding to each injection of the injection prescription data (see column 9, lines 63-67).

8. As per claim 15, Engleson teaches the apparatus of claim 10 as described above, further comprising a reader operable to read an identification code for identifying each injection, wherein said controller is operable to display a progress situation of mixing work on said display in accordance with the identification code read by the reader when conducting the mixing work of the injection (see column 7, lines 44-52).

9. As per claim 18, Engleson teaches the apparatus of claim 10 as described above, further comprising a reader operable to read a prescription identification code for identifying each injection prescription data, wherein said controller is operable to read the corresponding

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injection prescription data in accordance with the prescription identification code and displays it on the display (see column 7, lines 44-52).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Merki et al., U.S. Patent No. 5,002,055.

12. As per claim 11, Engleson et al. teach the apparatus of claim 10 as described above. Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

13. As per claim 16, Engleson teaches the apparatus of claim 15 as described above, wherein the controller decides whether the injection is proper or not in accordance with the identification code of the injection read by the reader and if improper, displays it on the display (see column 7, lines 52-59). Engleson does not explicitly teach storing pH-values data for each injection and determining the mixing order of the injections in accordance with the pH-values

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data. Merki teaches storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

14. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Mayaud, U.S. Patent No. 5,845,255.

15. As per claim 4, Engleson teaches the apparatus of claim 1 as described above. Engleson does not explicitly teach storing incompatibility data for showing whether or not two kinds of injections are incompatible and displaying the incompatibility on the display. Mayaud teaches storing incompatibility data showing whether or not a combination of two kinds of injections is incompatible, and wherein the controller decides whether or not a combination of two kinds of injections contained in injection prescription data for a patient is incompatible in accordance with the incompatibility data and displays it on a display (see column 31, lines 19-24). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to incorporate the incompatibility detection feature of Mayaud into the invention of Engleson. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

16. As per claim 8, Engleson in view of Mayaud teach the system of claim 4 as describe above. Engleson does not explicitly teach inputting new incompatibility data and storing it in the combination related data of the memory. Mayaud teach inputting new incompatibility data in

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addition to stored incompatibility data and storing it in a combination related data in memory (see column 31, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to make add this feature to the system of Engleson for the reasons given above with respect to claim 4.

Response to Arguments

17. In the remarks filed 7/30/03 in paper number 6, Applicants argue in substance that (1) Engleson does not teach an apparatus that supports injection mixing work before injections are mixed in a medical facility; (2) Engleson does not teach a combination data file corresponding to how a plurality of injections will react when combined with one another; (3) Merki does not teach determining the mixing order of injections based on the pH-values for each injection; (4) Mayaud does not teach certain features recited in claim 10.

18. In response to Applicants' argument (1), the Examiner respectfully submits that it is not clear from the limitations recited in the claims that an apparatus "supports" injection mixing work before injections are mixed in a medical facility. Applicants assert that this limitation is present in the recitation of "the controller is operable to determine a mixing order of the injections," however, the Examiner respectfully disagrees. This limitation merely recites a controller that determines a mixing order in accordance with the combination related data. Moreover, "combination related data" is only defined as "data corresponding to each injection." The system of Engleson includes a controller that determines and displays the mixing order of injections for various patients. Examples of this are clearly shown in Figures 9 and 10 which show a mixing order of injections in accordance with data corresponding to each injection. Therefore, Applicants' assertion that Engleson does not teach a controller that determines a

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mixing order before injections are mixed at a medical facility does not distinguish the claims, as currently recited, from the applied prior art.

19. In response to Applicants' argument (2), it is noted by the Examiner that claim 10 does not recite "a combination data file corresponding to how a plurality of injections will react when combined with one another." As noted above in response to argument (1), claim 10 merely defines "combination related data" as "data corresponding to each injection. It appears that claim 13 includes a limitation that most closely resembles this feature (a controller that determines whether or not two kinds of injections are incompatible). However, the Examiner has relied upon the teachings of Mayaud in combination with the teachings of Engleson for this feature. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, this argument is not persuasive in view of the rejections applied by the Examiner.

20. In response to Applicants' argument (3), the Examiner respectfully disagrees with Applicants' interpretation of the teachings of Merki. In particular, Applicants assert that Merki merely discloses a gastric pH sensor for intraluminally measuring the H⁺-ion activity of gastric juices. However, not only does the Merki reference teach sensing pH levels, but it also teaches adjusting the mixing of certain injections in response to obtained pH data (see column 3, lines 52-66). Therefore, the Examiner respectfully submits that the combination of the teachings of Engleson and Merki disclose this feature.

21. In response to Applicants' argument (4), the Examiner respectfully submits that the teachings of Mayaud have not been applied to the limitations recited in claim 10. Therefore, this argument is not persuasive in view of the rejections applied by the Examiner.

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Conclusion


22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

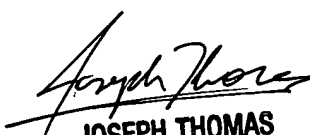
23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

26. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.


CLG
8/13/03


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